DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 10, 2015

Varian Medical Systems, Inc.
% Mr. Peter Coronado
Director, Regulatory Affairs
911 Hansen Way
PALO ALTO CA 94304

Re: K141624
Trade/Device Name: Interstitial Plastic Needles
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: January 7, 2015
Received: January 23, 2015

Dear Mr. Coronado:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141624

Device Name
Interstitial Plastic Needles

Indications for Use *(Describe)*
The interstitial plastic needles with 2mm diameter are designed for interstitial treatment in areas such as the head and neck, gynaecological, breast and prostate.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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PREMARKET NOTIFICATION

510(k) Summary

Plastic Interstitial Needles

As required by 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E-110 Palo Alto CA94304 Contact Name: Peter J. Coronado Phone: 650/424.6230 Fax: 650/646.9200
Date:	30th May 2014
Proprietary Name:	Plastic Needles with Mandrin, 2.0 mm diameter,
Classification Name:	Remote controlled radionuclide applicator system 21CFR892.5700 Class II
Common/Usual Name:	Plastic Needle, Interstitial Needle, Brachytherapy Needle, Interstitial plastic needle with 2mm diameter.
Predicate Devices:	K120341 Plastic Needle with Mandrin 2.0 Diameter Length 113mm
Device Description:	The Plastic Interstitial Needles with mandrin, ø 2.0 mm diameter, are designed for interstitial radiotherapy treatments. They are compatible with Varian afterloaders and can be used in combination with the appropriate accessories. They are intended to be used by trained and qualified personnel such as Radiation Oncologists, Physicians, Radiologists, Dosimetrists, Medical Physicists, and Nurses/MTRAs/Radiology Technicians/Radiographers in a hospital environment.
Indications for Use:	The interstitial plastic needles with 2mm diameter are designed for interstitial treatment in areas such as the head and neck, gynaecological, breast and prostate.

Technological Characteristics:

	GM11007560, 7570, 7580 Interstitial plastic needles	***GM11007560, 7570, 7580 Interstitial plastic needles and GM11010750 Plastic needle with mandrin, 2.0 mm diameter, 320 mm length, blunt tip***
Predicate Device Clearance Number:	K120341	N/A
Compatible Afterloader	GammaMed plus GammaMed 12(i) VariSource	GammaMed plus VariSource GammaMed 12(i) (Not with blunt tip needle).
Intended use	The interstitial plastic needles with 2mm diameter are designed for interstitial brachytherapy treatment in areas such as the head and neck, gynecological, breast and prostate.	The interstitial plastic needles with 2mm diameter are designed for interstitial brachytherapy treatment in areas such as the head and neck, gynecological, breast and prostate.
Indications for Use	The interstitial plastic needles with 2mm diameter are designed for interstitial brachytherapy treatment in areas such as the head and neck, gynecological, breast and prostate.	The interstitial plastic needles with 2mm diameter are designed for interstitial brachytherapy treatment in areas such as the head and neck, gynecological, breast and prostate.
Design	Plastic needle: • Diameter: 2 mm • Length: 113, 200, 320mm • Tip style: Sharp tip	Plastic needle: • Diameter: 2 mm • Length: 113, 200, 320mm • Tip styles: Sharp tip Blunt tip (320mm length only)
Materials	Needles: PEEK/Titanium Obturator/Mandrin: Stainless Steel	Needles: PEEK/Titanium Obturator/Mandrin: Stainless Steel,
Packing	individual	individual
Sterility	Provided non sterile	Provided non sterile
Sterilization method	Steam sterilization up to 25 times (15 cycles when using 18 minutes at 134°C)	Steam sterilization up to 25 times (15 cycles when using 18 minutes at 134°C)
Biocompatibility	Full biocompatibility	Full biocompatibility
Anatomical sites	Head and neck, gynecological, breast and prostate	Head and neck, gynecological, breast and prostate
Compatibility with the environment and other devices	CT compatible, MR conditional 1.5 and 3 T	CT compatible, MR conditional 1.5 and 3 T
Where used	Brachytherapy treatment room	Brachytherapy treatment room

Non Clinical Tests Bench Testing has been performed to demonstrate that

- the device functions correctly with the specified afterloaders;
- the device can withstand the number of cycles of use that it will experience in its lifetime;
- the device enables the radioactive source to be located to the accuracy required,
- the device is constructed of materials that are not significantly affected by the radiation to which they are exposed in the lifetime of the product;
- the device may be sterilized effectively
- the device can be used and sterilized for the specified number of times
- the positional accuracy of the source within the applicator is adequate.

Usability was assessed to the requirements of IEC 62366:2007.
Results of Bench Testing showed conformance to applicable requirements and specifications

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Clinical Tests No clinical tests have been included in this pre-market submission.

Conclusions All the tests that were performed met the applied pass criteria. Varian considers the devices to be safe and effective and to perform as well or better than the predicate